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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/975,020 | 10/12/2001 | Alan J. Magill | P66822US0 (WRAIR 98-40/46 | 7596 |

7590 02/24/2004

Office of the Staff Judge Advocate
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-JA (Ms. Elizabeth Arwine)
504 Scott Street
Fort Detrick, MD 21702-5012

| EXAMINER | |
|---|---|
| SHAHNAN SHAH, KHATOL S | |
| **ART UNIT** | **PAPER NUMBER** |
| 1645 | |

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/975,020 | MAGILL ET AL. | |
| | Examiner | Art Unit | |
| | Khatol S Shahnan-Shah | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *25 November 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *4,11,12,22-25 and 29-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,11,12,22-25 and 29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11/25/03* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

**1.** Applicants' amendment, received 11/25/2003 is acknowledged. Claims 4, 12, 22-25 and 30 were amended. Claim 18 was canceled. New claim 31 was added.

**2.** Currently claims 4, 11, 12, 22-25 and 29-31 are pending and under consideration.

### *Prior Citations of Title 35 Sections*

**3.** The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

### *Information Disclosure Statement*

**4.** The information disclosure statement filed 9/25/2002. The applicants resubmitted the missing references. The Examiner has considered the references. See attached PTO 1449.

### *Rejections Moot*

**5.** Rejection of claim 18 under 35 U.S.C. 112, first paragraph, made in paragraph 6 of the office action mailed 8/26/2003 is moot in view of cancellation of the claim.

**6.** Rejection of claim 18 under 35 U.S.C. 112, second paragraph, made in paragraph 8 of the office action mailed 8/26/2003 is moot in view of cancellation of the claim.

**7.** Rejection of claim 18 under 35 U.S.C. 102(b) made in paragraph 10 of the office action mailed 8/26/2003 is moot in view of cancellation of the claim.

### *Rejections Withdrawn*

**8.** Rejection of claims 22-25 under 35 U.S.C. 112, first paragraph, made in paragraph 6 of the office action mailed 8/26/2003 is withdrawn in view of applicants' amendment.

**9.** Rejection of claims 4, 11, 12, 22-25, 29 and 30 under 35 U.S.C. 112, second paragraph, made in paragraph 8 of the office action mailed 8/26/2003 is withdrawn in view of applicants' amendment.

***Rejections Maintained***

**10.** Rejection of claims 4, 11, 12, 22-25, 29 and 30 under 35 U.S.C. 102(b), made in paragraph 10 of the office action mailed 8/26/2003 is maintained.

The rejection was as stated below:

Claims 4, 11, 12, 22-25 and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Leishmania Research project DoD-8B (copy attached) or Stitler et al. (Production of Leishmania Skin Antigen Test GMP Protocol requirements 1 and 2, 1994 and 1995). Claims are drawn to a microfluidized lysate preparation from a least one Leishmania parasite.

Leishmania Research project DoD-8B and Stitler et al teach a microfluidized lysate preparation from Leishmania parasite manufactured in May 1995 (see attached papers specially abstract #300, page 186, 44th Annual Meeting of American Society of Tropical Medicine and Hygiene). The prior art teaches the claimed product. Limitations such as use of the product in kits or pharmaceutical composition will be inherent in the teachings of Leishmania Research project DoD-8B.

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430

(CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicants' arguments filed November 25, 2003 have been fully considered but they are not persuasive.

Applicants argue that the microfluidized lysate preparation of the prior art is the first generation and the preparation of present invention is a second-generation preparation. Applicants further argue, "The cited prior art only discloses the general procedure for making the first generation lysate preparation. Nowhere do the cited prior art teach or suggest microfluidized lysate preparation that are free of dextran." Applicants further argue "Nowhere do the cited prior art teach or suggest microfluidized lysate preparation that is suitable for suitable for reliable assays."

It is the examiner's position that the cited prior art teaches the invention as claimed by the applicant. The cited prior art (Project DoD-8B) teaches and has completed both phase I and II of the of development of LSTA. In 1999 the second generation of the lysate was reformulated into a liquid product (i.e. phenol) to avoid a suspected hypersensitivity to a component of the lyophilization buffer (i. e. dextran). A new IND for this reformulated liquid microfluidized lysate (MFL)-LSTA was submitted to FDA in 1999 (see attached Project Summary).

***Conclusion***

**11.** No claims are allowed

**12.** **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

**13.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

February 20, 2004

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER